Docket No.: C1233.70001US01 (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Alejandro Balazs et al.

Application No.: 10/577,177
Confirmation No.: 4085

Filed: February 5, 2007

For: METHODS FOR PURIFYING HEMATOPOIETIC STEM CELLS

Examiner: M. A. Belyavskyi

Art Unit: 1644

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I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filling system in accordance with 37 CFR \$ 1.6(a)(4).

Dated: November 17, 2011 Electronic Signature for Paula J. Bramwell: /Paula J. Bramwell:

## APPLICATION FOR PATENT TERM ADJUSTMENT

Mail Stop Issue Fee Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450

Dear Sir

Applicant respectfully requests reconsideration of the Patent Term Adjustment (PTA) indicated in the Determination of Patent Term Adjustment mailed with the Notice of Allowance from the United States Patent and Trademark Office (USPTO) on May 26, 201. It is respectfully requested that Applicant be granted a patent term adjustment of at least 646 days instead of 131 days. Pursuant to the requirements under 37 C.F.R. §1.705(b), Applicant is providing the required fee set forth in 37 C.F.R. §1.18(e) and a statement of the facts involved.

The issue fee has not yet been paid and is submitted herewith.

 As of the mailing of the Notice of Allowance, the correct PTA is 646 days and not 131 days as calculated by the USPTO. In calculating the PTA, the USPTO failed to include the period of delay under 37 C.F.R. §1.702(b) directed to the failure to issue a patent within three years of the actual filing date of the application.

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 Under 37 C.F.R. §1.703(a)-(f), the current period of adjustment due to examination delay is as follows:

- a. A period of 75 days under 37 C.F.R. §1.703(a)(1) due to the failure of the USPTO to mail either an action under 35 U.S.C. §132 or a notice of allowance under 35 U.S.C. §151 not later than 14 months from the date the application was filed under 35 U.S.C. §111(a) or fulfilled the requirements of 35 U.S.C. §371.
- b. A period of 228 days under 37 C.F.R. §1.703(a)(2) due to the failure of the USPTO to mail either an action under 35 U.S.C. §132 or a notice of allowance under 35 U.S.C. §151 not later than 4 months from the date a reply in compliance with \$1.113(c) was filed.
- c. A period of 516 days under 37 C.F.R. §1.703(b) due to the failure of the USPTO to issue a patent on the instant application not later than three years after the date on which the application was filed under 35 U.S.C. §111(a) or the national stage commenced under 35 U.S.C. §371(b) or (f) in an international application. The three year post-filing anniversary date is 04-25-2009. A Request for continued examination was filed on 09-24-2010. The number of days between these days is 516.
- d. Under 37 C.F.R. §1.703(f), the term of a patent shall be adjusted for the sum of the periods calculated under paragraphs 37 C.F.R. §1.703(a) through (e), to the extent that such periods are not overlapping, less the sum of the periods calculated under 37 C.F.R. §1.704. Of the delays currently attributable to the USPTO, 1 day under 37 C.F.R. §1.703(a)(1) and (a)(2) overlaps with those under 37 C.F.R. §1.703(b).
- e. Thus, the current total period of USPTO examination delay is 818 days which is the sum of the delays enumerated in paragraphs 2(a), (b) and (c) minus the overlapping delay as shown in paragraph 2(d).

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 Pursuant to 37 C.F.R. §1.704, the current total period of USPTO delay is reduced by the period of Applicant delay, which the USPTO determines to be 172 days.

- Accordingly, the current correct patent term adjustment is 646 days which is the current total period of USPTO delay (818 days) minus the period of Applicant delay (172 days).
- 5. Applicant notes that the errors in the USPTO's patent term adjustment calculation methodology have been consistently applied by the USPTO in making all patent term adjustment calculations. Those methods, however, are contrary to the statute as detailed in the Memorandum and Order entered by the United States District Court for the District of Columbia in Wyeth v. Dudas, Civil Action No. 07-1492 (D.D.C. Sept. 30, 2008), in which the Court granted summary judgment holding the USPTO's patent term adjustment methodology was erroneous as a matter of law.
- 6. The correct patent term adjustment methodology, as determined in Wyeth v. Dudas, governs the USPTO's calculation of the patent term adjustment for the patent expected to issue in the instant application. Applicant's patent term adjustment methodology, as outlined above, is consistent with the correct patent term adjustment methodology determined in Wyeth v. Dudas.
- The expected patent that will issue from the instant application is not subject to a terminal disclaimer.

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Applicant submits the fee of \$200.00 for filing an application for patent term adjustment as set forth in 37 CFR § 1.18(e). Please charge any fee deficiency, or credit any overpayment to our Deposit Account No. 23/2825 under Docket No. C1233.70001US01 from which the undersigned is authorized to draw.

Dated: November 17, 2011 Res

Respectfully submitted,

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